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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,563	09/26/2003	Gerhardt Kumpfe	06478.1494	8137
22852 7590 05/06/2009 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
EXAMINER KAM, CHIH MIN				
ART UNIT 1656		PAPER NUMBER		
MAIL DATE 05/06/2009		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/670,563

## Applicant(s)

KUMPE ET AL.

## Examiner

CHIH-MIN KAM

## Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-12, 15 and 19-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-34 is/are allowed.
- 6) ☒ Claim(s) 10-12, 15 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 10-12, 15 and 19-34 are pending.

Applicants' amendment filed January 30, 2009 is acknowledged. Applicants' response has been fully considered. Claim 10 has been amended, claims 1-9, 13 and 16-18 have been cancelled, and new claims 25-34 have been added. Therefore, claims 10-12, 15 and 19-34 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claim 13 is withdrawn in view of applicants' cancellation of the claims, and applicants' response at page 6 in the amendment filed January 30, 2009.

### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 10-13, 15 and 19-24 under 35 U. S. C. 112, first paragraph, enablement, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 11-16 in the amendment filed January 30, 2009.
4. The previous rejection of claim 13 under 35 U. S. C. 112, first paragraph, new matter, is withdrawn in view of applicants' cancellation of the claims, and applicants' response at pages 6-11 in the amendment filed January 30, 2009.

### **New Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 10-12, 15 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 10-12, 15 and 19-24 are directed to a process for producing a concentrate of a factor VIII:C-containing von Willebrand factor (vWF/FVIII:C), comprising subjecting a liquid comprising factor VIII:C (FVIII:C) and von Willebrand factor (vWF) to a fractional precipitation using of at least one of an alkali metal salt or an alkaline earth metal salt, and an amino acid chosen from glycine,  $\alpha$ - or  $\beta$ -alanine,  $\alpha$ - or  $\beta$ -, or  $\gamma$ -aminobutyric acid, lysine, valine, asparagine, and glutamic acid, wherein the fractional concentration of the amino acid is from about 67 to about 110 g/l and the fractional concentration of the alkali metal or the alkaline earth metal salt is from about 100 to about 160 g/l, such that the produced concentrate has an increased content of high molecular weight multimers of vWF, and a ratio of von Willebrand factor ristocetin cofactor activity (vWF:RCof) to von Willebrand factor antigen (vWF:Ag) of greater than 1.

While the specification indicates the precipitation of the vWF/FVIII:C-containing precipitate was carried out with concentration of from 70 to 160 g/l glycine and from 100 to 160 g/l sodium chloride (page 7, lines 29-32), the final concentration of NaCl in the precipitation of the vWF/FVIII:C fraction reached 122 g/l (Example 1; page 10, lines 10-21) or 122.2 g/l (Example 2; page 12, lines 24-29) and the fractional concentration of the alkali metal or the alkaline earth metal salt is from 100 to 160 g/l (original claim 13), the specification does not disclose the fractional concentration of the alkali metal or the alkaline earth metal salt is from

about 100 to about 160 g/l. Furthermore, the specification does not define the term “about” for the fractional concentration of the alkali metal or the alkaline earth metal salt. The lack of description of the fractional concentration of the alkali metal or the alkaline earth metal salt is from about 100 to about 160 g/l, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

*Response to Arguments*

Applicants have argued regarding the term “the fractional concentration of the amino acid in the precipitation is from about 67 to about 110 g/l” recited in the cancelled claim 13 and the amended claim 10, and new claim 25 recites “the fractional concentration of the amino acid in the precipitation is from 67 to 110 g/l”. Applicants indicate although the specification does not literally recite these ranges of fraction concentration of amino acid, applicant has narrowed a range recited in the specification based on the operable embodiments disclosed in the Examples, e.g., using the amino acid concentrations of 66.7, 71.1, 80, 90, 90.4 and 109.6 g/l, all of which produced vWF:RCof/vWF:Ag ratios greater than 1 (Examples, 1, 2 and 4). Furthermore, the original claim 13 recites the fractional concentration of the amino acid is from 70 to 160 g/l and the fractional concentration of the alkali metal or the alkaline earth metal salt is from 100 to 160 g/l. Thus, the originally filed specification provides adequate support for the fractional concentration of amino acid recited in claim 10 and 25, and the rejection should be withdrawn (pages 6-11 of the response).

Applicants' response has been fully considered, regarding "the fractional concentration of the amino acid in the precipitation is from about 67 to about 110 g/l", the arguments are found persuasive, thus there is no rejection with respect to this term. However, regarding the term "the fractional concentration of the alkali metal or the alkaline earth metal salt is from about 100 to about 160 g/l", the specification does not provide adequate support (see above). Thus, applicants have failed to sufficiently describe the claimed invention, and claims 10-12, 15 and 19-24 are rejected.

#### ***Conclusion***

6. Claims 10-12, 15 and 19-24 are rejected; and claims 25-34 are free of art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

May 4, 2009